FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AVENTIS Pharmaceuticals, Inc., MERRELL Pharmaceuticals, Inc., and CARDERM CAPITAL L.P., Plaintiffs,	**OPINION**
BARR LABORATORIES, INC., Defendant.	Civil Action No. 01-3627 (JAG)
IMPAX LABORATORIES, INC., Defendant.	Civil Action No. 02-1322 (JAG)
TEVA PHARMACEUTICALS, USA, INC., Defendant.	Civil Action No. 03-487 (JAG)
MYLAN PHARMACEUTICALS, INC., Defendant.	Civil Action No. 03-1179 (JAG)
DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Defendants.	Civil Action No. 03-1180 (JAG)

APPEARANCES:

Gerald Sobel, Esq.
Joel Katcoff, Esq.
David K. Barr, Esq.
Kaye Scholer LLP
425 Park Avenue
New York, New York 10022-3598

Tricia B. O'Reilly, Esq.
Liza M. Walsh, Esq.
Connell Foley LLP
85 Livingston Avenue
Roseland, New Jersey 07065

ATTORNEYS FOR PLAINTIFFS AVENTIS PHARMACEUTICALS INC., MERRELL PHARMACEUTICALS INC., AND CARDERM CAPITAL, L.P.

Richard S. Gresalfi, Esq.
Steven J. Lee, Esq.
William G. James, Esq.
Kenyon & Kenyon
One Broadway
New York, New York 10004

Allyn Z. Lite, Esq.
Lite, DePalma, Greenberg & Rivas, LLC
Two Gateway Center
Newark, New Jersey 07102

ATTORNEYS FOR DEFENDANT IMPAX LABORATORIES, INC. AND TEVA PHARMACEUTICALS USA, INC.

Glenn J. Pfadenhauer, Esq.
George A. Borden, Esq.
Bonnie Dunninger Nathan, Esq.
David I. Berl, Esq.
Williams & Connolly, LLP
725 Twelfth Street N.W.
Washington, D.C. 20005

Robert M. Goodman, Esq.
C. Brian Kornbrek, Esq.
Greenbaum, Rowe, Smith & Davis, LLP
Metro Corporate Campus, 99 Wood Ave. South
Woodbridge, New Jersey 07095

ATTORNEYS FOR DEFENDANT BARR LABORATORIES, INC.

E. Anthony Figg, Esq.
Elizabeth A. Leff, Esq.
Rothwell, Figg, Ernst & Manbeck
1425 K Street, N.W.
Washington, D.C. 20005

Arnold B. Calmann, Esq.
Jeffrey Soos, Esq.
Saiber, Schlesinger, Satz & Goldstein, LLC
One Gateway Center
Newark, New Jersey 07102

ATTORNEYS FOR DEFENDANT MYLAN PHARMACEUTICALS, INC.

Thomas G. Roth, Esq.
Law Offices of Thomas G. Roth
395 Pleasant Valley Way
West Orange, New Jersey 07052

Thomas C. Pontani, Esq.
Martin B. Pavane, Esq.
Alfred H. Hemingway, Jr., Esq.
Cohen Pontani Lieberman & Pavane
551 Fifth Avenue
New York, New York 10176

ATTORNEYS FOR DEFENDANTS DR. REDDY'S LABORATORIES, LTD. AND DR. REDDY'S LABORATORIES, INC.

GREENAWAY, JR., U.S.D.J.

This is a patent infringement suit in which Aventis Pharmaceuticals, Inc. ("Aventis"), Merrell Pharmaceuticals, Inc., and Carderm Capital, L.P. (collectively "Plaintiffs") have sued generic drug manufacturers, Barr Laboratories, Inc. ("Barr"), Impax Laboratories, Inc. ("Impax"), Teva Pharmaceuticals USA, Inc. ("Teva"), Mylan Pharmaceuticals, Inc. ("Mylan"), Dr. Reddy's Laboratories, Ltd., and Dr. Reddy's Laboratories, Inc. ("Reddy") (collectively "Defendants") for infringement of U.S. Patent Nos. 5,738,872 ("the '872 patent"), 6,113,942 ("the '942 patent"), 5,855,912 ("the '912 patent"), 5,932,247 ("the '247 patent"), and 6,039,974 ("the '974 patent") which disclose solid unit dosage fexofenadine formulations sold in the United States under the tradenames ALLEGRA® and ALLEGRA-D®. Defendants filed a motion for summary judgment, pursuant to FED. R. CIV. P. 56, on their counterclaim that claims 1 and 2 of the '872 patent are invalid as anticipated, and that the '872, '912, '942, and '247 patents are not infringed.

On June 30, 2004, this Court issued an opinion granting Defendants' motion for summary judgment against Plaintiffs for non-infringement of the '942 patent, the '912 patent, and the '247 patent. Aventis Pharms., Inc. v. Barr Labs., Inc., 335 F. Supp. 2d 558, 586 (D.N.J. 2004) [hereinafter "Summary Judgment Opinion"]. A ruling on the validity of claims 1 and 2 of the '872 patent was reserved pending a Markman hearing to resolve disputes regarding the construction of claims 1 and 2 of the patent. Id. at 585.

The Court held a Markman hearing on September 9, 2004, September 21, 2004, September 24, 2004, and September 28, 2004 ("the Markman hearing") to resolve the issue of whether claims 1 and 2 of the '872 patent impart a product limitation of a disintegrant incorporated into the granules of the resulting product (i.e., separate intragranular disintegrant).

After reviewing the reports of Plaintiffs' expert witness, Dr. Zak T. Chowhan, and Defendants' expert witness, Dr. Garnet E. Peck, and their respective testimony at the Markman hearing, this Court concluded that "one can practice the steps recited in claim 1 or 2, create a granulation, mill the granulation into powder form" and produce a powder that "do[es] not contain granules[,]" and therefore "do[es] not contain separate intragranular disintegrants." Aventis Pharms., Inc. v. Barr Labs., Inc., 341 F. Supp. 2d 502, 511 (D.N.J. 2004) [hereinafter "Markman Opinion"]. The Court concluded that the claims do not impart a limitation requiring the presence of a separate intragranular disintegrant. Id.

BACKGROUND

Presently before the Court is Defendants' renewed motion for summary judgment. The motion asserts that claims 1 and 2 of the '872 patent are anticipated by prior art references U.S. Patent Nos. 4,929,605 ("the '605 patent"), 4,996,061 ("the '061 patent"), 6,037,353 ("the '353 patent"), 5,375,693 ("the '693 patent"), and 4,254,129 ("the '129 patent") and, are thus, invalid under 35 U.S.C. § 102 (b).

I. STANDARD OF REVIEW

A. *Standard for Summary Judgment*

Summary judgment is appropriate under FED. R. CIV. P. 56(c) when the moving party demonstrates that there is no genuine issue of material fact and the evidence establishes the moving party's entitlement to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986); Orson, Inc. v. Miramax Film Corp., 79 F.3d 1358, 1366 (3d Cir. 1996). In making this determination, the Court must draw all reasonable inferences in favor of the non-movant. Hullett v. Towers, Perrin, Forster & Crosby, Inc., 38 F.3d 107, 111 (3d Cir. 1994); Nat'l

State Bank v. Fed. Reserve Bank of N.Y., 979 F.2d 1579, 1581 (3d Cir. 1992).

Once the moving party has satisfied its initial burden, the party opposing the motion must establish that a genuine issue as to a material fact exists. Jersey Cent. Power & Light Co. v. Lacey Township, 772 F.2d 1103, 1109 (3d Cir. 1985). The party opposing the motion for summary judgment cannot rest on mere allegations and instead must present actual evidence that creates a genuine issue as to a material fact for trial. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986); Siegel Transfer, Inc. v. Carrier Express, Inc., 54 F.3d 1125, 1130-31 (3d Cir. 1995). "[U]nsupported allegations . . . and pleadings are insufficient to repel summary judgment." Schoch v. First Fid. Bancorporation, 912 F.2d 654, 657 (3d Cir. 1990); see also FED. R. CIV. P. 56(e) (requiring nonmoving party to "set forth specific facts showing that there is a genuine issue for trial").

If the nonmoving party has failed "to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial, . . . there can be 'no genuine issue of material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." Katz v. Aetna Cas. & Sur. Co., 972 F.2d 53, 55 (3d Cir. 1992) (quoting Celotex, 477 U.S. at 322-23). In determining whether there are any issues of material fact, the Court must resolve all doubts as to the existence of a material fact against the moving party and draw all reasonable inferences – including on issues of credibility – in favor of the nonmoving party. Watts v. Univ. of Del., 622 F.2d 47, 50 (3d Cir. 1980).

B. ***Anticipation***

A claim is invalid as anticipated if a single prior art reference published more than a year before the patent application was filed discloses each and every limitation set forth in a claim, either expressly or inherently.[1] In re Schreiber, 128 F.3d 1473, 1477 (Fed. Cir. 1997). A patent is presumed valid when issued. 35 U.S.C. § 282. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity. Id. The presumption of patent validity may be rebutted only by clear and convincing evidence. Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1050 (Fed. Cir.), cert. denied, 488 U.S. 825 (1988) (citations omitted).

Anticipation is a question of fact. Medical Instrumentation and Diagnostics Corp. v. Elektra AB, 344 F.3d 1205, 1221 (Fed. Cir. 2003) ("[t]he question of what a reference teaches and whether it describes every element of a claim is a question for the finder of fact."). Summary judgment is appropriate on a question of validity when the party challenging validity has shown by clear and convincing evidence facts supporting a conclusion of invalidity. Ryco, Inc. v. Ag-Bag Corp., 857 F.2d 1418, 1423 (Fed. Cir. 1988) (citing American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1360 (Fed. Cir.), cert. denied, 469 U.S. 821 (1984)).

As explained in Scripps Clinic & Research Found. v. Genentech, Inc., "[i]nvalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. There must be no difference between the claimed invention and the reference

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[1] "A person shall be entitled to a patent unless –
. . . (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102 (b).

disclosure, as viewed by a person of ordinary skill in the field of the invention." 927 F.2d 1565, 1576 (Fed. Cir. 1991) (citations omitted).

> Anticipation is a question of fact. To make such finding on summary judgment the court must determine that no facts material to the question are disputed; or that even if all material factual inferences are drawn in favor of the non-movant, there is no reasonable basis on which the non-movant can prevail. The standard of proof that would have to be met at trial must be considered.

Id. (citations omitted).

Thus, to find claims 1 and 2 of the '872 patent invalid as anticipated by prior art, this Court must find that even if all material factual inferences are drawn in favor of the Plaintiffs, there is no reasonable basis on which Plaintiffs can prevail.

II. DISCUSSION

In their renewed motion for summary judgment, Defendants assert that claims 1 and 2 of the '872 patent are invalid as anticipated. Plaintiffs argue that the prior art references, the '061, '129, '353, '605 and '693 patents, fail to anticipate because they do not disclose each and every element of claims 1 and 2 of the '872 patent. Plaintiffs further argue that this Court should deny Defendants' renewed motion for summary judgment on the grounds that genuine issues of fact remain in dispute as to three material inquiries. First, Plaintiffs argue that none of the five patents identified by Defendants as prior art discloses a tablet formulation of fexofenadine hydrochloride that contains a separate intragranular disintegrant or a powder formulation that contains a disintegrant. Second, Plaintiffs assert that the '061, '129, '353, and '693 patents do not disclose a binder that is water soluble, and therefore, these patents fail to disclose a pharmaceutical composition made with a "solution of a binding agent" which is disclosed in claims 1 and 2 of the '872 patent. Third, Plaintiffs contend that the '129, '353, and '693 patents

fail to disclose the limitations of claims 1 and 2 of the '872 patent, as arranged in the claims.[2]

For the reasons set forth below, this Court finds that the five prior art references cited by Defendants anticipate claims 1 and 2 of the '872 patent. This Court grants Defendants' motion for summary judgment.

A. *Plaintiffs Cannot Defeat Summary Judgment by Asserting a Product Limitation of a Tablet with a Separate Intragranular Disintegrant*

Plaintiffs argue that "[t]o anticipate a product-by-process claim, the reference must describe a product that can be made by the recited process steps." (Pls.' Br. Opp'n Defs.' Mot. Summ. J., at 2.) Referring to this Court's Markman Opinion, Plaintiffs argue that the '872 patent discloses a powder formulation of the claimed pharmaceutical composition containing a disintegrant and a non-powder formulation (e.g., a tablet) of the claimed pharmaceutical composition containing a separate intragranular disintegrant. Plaintiffs reason that the cited prior art references, the '061, '605, '129, '353, and '693 patents, do not disclose a powder formulation of fexofenadine hydrochloride with a disintegrant or a tablet formulation with a separate intragranular disintegrant, and therefore, cannot anticipate claims 1 and 2 of the '872 patent.

Plaintiffs contend that "a tablet made by incorporating a separate intragranular disintegrant" results in a different product, a product that is physically and functionally distinct from "a tablet made without incorporating an intragranular disintegrant." (Id. at 7.) Prior art references that fail to disclose powder formulations of the pharmaceutical composition with a

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[2] While Plaintiffs present three arguments against the five patents generally, Plaintiffs' opposition papers reflect that only certain arguments are applicable to certain of the five identified prior art references. (Pls.' Br. Opp'n Defs.' Mot. Summ. J., at 6-25.) Plaintiffs do not argue that the '605 patent fails to disclose a "solution of a binding agent." (Id. at 6-13.) In addition, Plaintiffs do not argue that the '601 and '605 patents fail to anticipate because the elements are not "arranged as in claims." (Id. at 6-14.)

disintegrant or tablet formulations with a separate intragranular disintegrant do not describe the product made by the process steps of claims 1 and 2 and therefore, cannot anticipate, Plaintiffs argue. (Pls.' Br. Opp'n Defs.' Mot. Summ. J., at 7-9.)

As an initial matter, this Court must address certain legal and factual conclusions presented in Plaintiffs' characterization of the Markman Opinion. The '872 patent describes a fexofenadine hydrochloride drug formulation. Independent claims 1 and 2 of the '872 patent are product-by-process claims. Such claims are not specified in the statutes governing patents. This category of claims, product-by-process claims, is a judicial construct which has developed as a result of recognition that, due to the limitations of language, some products may be described only by the process used to make them.[3]

"In determining patentability we construe the product as not limited by the process stated in the claims." Scripps, 927 F.2d at 1583. As this Court has explained in earlier opinions in this matter "'the correct reading of product-by-process claims is that they are not limited to the product prepared by the process set forth in the claims.'" Aventis, 335 F. Supp. 2d at 581 (quoting Scripps, 927 F.2d at 1583).[4] "A novel product that meets the criteria of patentability is

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[3] For further discussion of product-by-process claims, see generally Richard A. Anderson and Lawrence A. Hymo, Product-by-Process Claims: Time for Reexamination, 3 Fed. Cir. B.J. 131 (1993).

[4] While a different panel of the Federal Circuit has held that process terms in product-by-process claims do serve as limitations in determining infringement, Atlantic Thermoplastics Co. v. Faytex Corp., 970 F.2d 834 (Fed. Cir. 1992), this Court continues to follow Scripps which was decided approximately one year before Atlantic Thermoplastics. See Aventis, 335 F. Supp. 2d at 581-582 n.21. Under Federal Circuit law, where there are conflicting precedents, the earlier precedent controls. See DeKalb v. Northrup King Co., No. 96C50169, 1997 WL 587492,*2 (N.D. Ill. Aug. 4, 1997) (applying the Federal Circuit's conflict rule, the court will apply Scripps); Trustees of Columbia Univ. v. Roche Diagnostics, 126 F. Supp. 2d 16, 32 (D. Mass. 2000) ("When confronted with two panel opinions in direct conflict, the earlier

not limited to the process by which it was made." Vanguard Prods. Corp. v. Parker Hannifin Corp., 234 F.3d 1370, 1372 (Fed. Cir. 2000). See also In re Thorpe, 777 F.2d 695, 697 (Fed. Cir. 1985) ("The patentability of a product does not depend on its method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.") (citations omitted). As this Court further explained in its Markman Opinion construing the claims of the '872 patent, "[c]laims cannot be 'saved' from invalidity by reading extraneous limitations not present in the claims." Aventis, 341 F. Supp. 2d at 505 (citations omitted). Differences between prior art and claimed products are only relevant to the extent that the characteristics are claimed. Aventis, 335 F. Supp. 2d at 582.

In the Markman Opinion, this Court resolved the issue of whether claims 1 and 2 of the '872 patent impart a product limitation of a disintegrant incorporated into the granules of the resulting product (i.e., a separate intragranular disintegrant). Claim 1 of the '872 patent reads:

> Claim 1: A pharmaceutical composition prepared by a wet granulation process comprising, preparing the wet granulation wherein a compound of formula: [graphic] wherein X is a number ranging from about zero to 5, and the individual optical isomers thereof, a diluent and a disintegrant are mixed with a solution of a binding agent; the wet granulation is screened, the wet granulation is dried, and the dry granulation is screened.

('872 patent, col. 33, lines 9-34.) Claim 2 is identical to Claim 1, except instead of reciting that "the dry granulation is screened," it recites that "the dry granulation is combined with a

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decision is controlling."); but see Tropix, Inc. v. Lumigen, Inc., 825 F. Supp. 7, 10 (D. Mass. 1993) ("It would appear to me, even in the confused state of the record, that a majority of the judges of the Federal Circuit would rule that Atlantic states the controlling law, and I so rule in this case.") Until the Scripps decision is rejected by a hearing en banc, it is the precedential decision. As the earlier panel opinion, Scripps is controlling and this Court follows its reasoning.

lubricant." ('872 patent, col. 33, lines 36-60.)

In determining the proper construction of the claims, this Court must examine the claim language, patent specification, and prosecution history on record. Aventis, 341 F. Supp. 2d at 507 (citing Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). The specification in Column 7 of the patent explains that:

> [t]he pharmaceutical composition of the present invention is administered orally in the form of a solid unit dosage. Examples of solid unit dosage forms are tablets, coated tablets, powders, dragees, hard or soft gelatin capsules and the like. The preferred solid unit dosage forms of the present invention are capsules, tablets and the like.

('872 patent, col. 7, lines 62-67).

After examining the intrinsic evidence, this Court evaluated voluminous testimony presented by both parties at the Markman hearing and received and reviewed a number of articles and studies. In support of their arguments proffered at the Markman hearing, Plaintiffs submitted the expert report of Zak T. Chowhan, Ph.D., and Defendants submitted the expert report of Garnet E. Peck, Ph.D.

On October 22, 2004, this Court issued the Markman Opinion and its conclusions regarding claim construction, finding that "one can practice the steps recited in claim 1 or 2, create a granulation, mill the granulation into powder form, and still be within the scope of [claims 1 and 2]." Aventis, 341 F. Supp. 2d at 511. A powder formulation, clearly listed in the specification as one of the embodiments of the pharmaceutical composition, can be produced by practicing the steps in claims 1 and 2. Because powders do not contain granules, and therefore do not contain separate intragranular disintegrants, this Court concluded that the patent does not impart a claim limitation requiring a separate intragranular disintegrant. Id.

For the Markman hearing and in the summary judgment proceedings, Plaintiffs filed four successive declarations of Dr. Chowhan. In his third declaration submitted by Aventis in support of their motion for reconsideration of this Court's Markman Opinion, Dr. Chowhan identifies several areas in which he disagrees with the Court's conclusions. However, as this Court noted in its opinion denying Plaintiffs' motion for reconsideration of the Markman Opinion, Dr. Chowhan's testimony in his third declaration contradicts his testimony at the Markman hearing and therefore, is not credible. Aventis Pharms., Inc. v. Barr Labs., Inc., No. 01-3627, 2004 WL 3142511, at *4 (D.N.J. Dec. 20, 2004).

In his third declaration, Dr. Chowhan asserts that no person skilled in the art would ever make granules using a wet granulation process only to grind those granules back into powder. (Third Decl. Dr. Chowhan, at ¶¶ 8-17). Yet, Dr. Chowhan testified during the Markman hearing that there may be circumstances that merit making granules using a wet granulation process and then grinding the granules back into powder, such as when one seeks to get a better distribution of the active ingredient amongst the other particles.[5] Aventis, 2004 WL 3142511, at *4. As indicated in this Court's opinion denying reconsideration of the Markman Opinion, the testimony of Plaintiffs' expert witness foreclosed the issue that Plaintiffs urge the Court to revisit. Having determined that powders are included among the embodiments of the pharmaceutical

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[5] Q: Doctor, you told me that there are reasons to use a granulation no matter what the final dosage form is to get a better distribution of your active amongst the other particles and you would get better distribution of a very small amount of active by making granulation, making granules, and milling that than you would as compared to dry blending, wouldn't you?

A: That is a special case when you have a low dose and you want to administer the drug in micrograms, or even up to a few milligrams.

(9/24/04 Hr'g Tr. at 93.)

composition in the '872 patent and that powders do not contain separate intragranular disintegrants, this Court denied Plaintiffs' motion for reconsideration of the Markman Opinion and affirmed the conclusion that the language of claims 1 and 2 does not impart a product limitation of a disintegrant incorporated into granules. Aventis, 341 F. Supp. 2d at 511 ("[c]onsequently, . . . the language of claims 1 and 2 does not impart a product limitation of a disintegrant incorporated into granules.")

During oral argument on Defendants' instant motion, Plaintiffs argued that the issues reviewed in the Markman Opinion are not relevant to the resolution of the present inquiry regarding anticipation. (3/7/05 Hr'g Tr. at 7-9.) According to Plaintiffs, this Court's holding, that one could practice the process steps in claims 1 and 2 of the '872 patent and produce a powder not containing a separate intragranular disintegrant, leaves unresolved the question of whether there is a separate intragranular disintegrant in other solid unit dosage forms of the product, such as tablets or capsules. (Id.)

Plaintiffs argue that this Court cannot reach the issue of anticipation because the meaning of the term "pharmaceutical composition" remains in dispute. According to Plaintiffs, a pharmaceutical composition, made by practicing claims 1 and 2, that is a tablet or a capsule with a separate intragranular disintegrant is physically and structurally distinct from a tablet or a capsule made without a separate intragranular disintegrant. Plaintiffs contend that Defendants' expert witness, Dr. Peck, admitted that there are physical and structural differences in a tablet with a separate intragranular disintegrant and one without a separate intragranular disintegrant. Dr. Peck acknowledged, Plaintiffs argue, that there is a difference in the distribution of the disintegrants in the finished tablet depending on where you originally placed the disintegrant

particles, within the granules as opposed to originally having them put outside the granules. (9/9/04 Hr'g Tr. 140-141.) Plaintiffs argue that Dr. Peck admitted that physical structural difference has an effect on how the tablet works. (Id.) Based on these admissions, Plaintiffs further argue that this Court should find that a tablet with a separate intragranular disintegrant cannot be compared to a tablet without a separate intragranular disintegrant, and because the products are different, one cannot anticipate the other.

As the Federal Circuit noted in Amgen, Inc., v. Hoechst Marion Roussel, Inc., it is the claims that measure the invention. 314 F.3d 1313, 1325 (Fed. Cir. 2003) (citing SRI Int'l v. Matsushita Elec. Corp., 775 F.2d 1107, 1121 (Fed. Cir. 1985) (en banc)). Differences that do not constitute claim limitations or product limitations imparted by characteristics or properties of the '872 patent will not preclude a finding of anticipation. Oakley, Inc. v. Sunglass Hut Intl, 316 F.3d 1331, 1339-1343 (Fed. Cir. 2003).

After carefully construing claims 1 and 2 at the Markman hearing, this Court concluded that the presence of a separate intragranular disintegrant is not a claim limitation. Column 7 in the specification indicates the pharmaceutical composition created by one practicing the process steps of claims 1 and 2 of the '872 patent may take the form of a tablet, a capsule, or a powder. Because the powder form of the pharmaceutical composition does not have the characteristic of a separate intragranular disintegrant in the product, this Court found no grounds for imparting such a limitation.

Plaintiffs ask the Court to apply different interpretations to the same term – pharmaceutical composition – based on the form of the product, i.e., tablet, capsule, or powder. Noting that this Court has found that there is no claim limitation requiring a separate

intragranular disintegrant in the powder form produced when one practices claims 1 and 2, Plaintiffs petition the Court to find that there is such a claim limitation when the product of the claims is a tablet or a capsule. This Court declines Plaintiffs' current entreaty to revisit issues resolved in the Markman Opinion and to construe pharmaceutical composition differently for each of the embodiments produced when the claims are practiced.

B. ___*Plaintiffs Cannot Defeat Summary Judgment by Proposing Claim Limitations Where None Exist*

Claims 1 and 2 of the '872 patent disclose a diluent and a disintegrant that are "mixed with a solution of a binding agent[.]" ('872 patent, col. 33, lines 31, 58.) Plaintiffs posit that claims 1 and 2 permit the use of only those binding agents capable of "going into a solution" or forming a granulating solution. (Pls.' Br. Opp'n Defs.' Mot. Summ. J., at 10.) Plaintiffs contend that the '061, '129, '353, and '693 patents describe pregelatinized starch mixed with water as the binding agent. According to Plaintiffs, the '061, '129, '353 and '693 patents fail to anticipate and fall outside the scope of the claims because they disclose binding agents that cannot make a granulating solution.

In fact, the cited prior art references disclose starch binders. The '061 patent describes a wet granulation in which terfenadine, microcrystalline cellulose, pregelatinized corn starch,[6] and calcium carbonate are granulated with a solution of polysorbate 80 in water. ('061 patent, col. 7, lines 7-18.) Example 10 of the '129 patent employs starch as a binding agent.[7] ('129 patent, col. 16, lines 55-68.) Finally, the '693 patent discloses lactose, starch, pregelatinized maize

[6] The pregelatinized starch is identified as Starch 1500. ('061 patent, col. 5, line 5.)

[7] The '353 patent incorporates the '129 patent by reference.

starch, and magnesium stearate. ('693 patent, col. 11, lines 19-30.)

According to Plaintiffs, a pregelatinized starch does not form a granulating solution; rather, it forms a paste. Plaintiffs argue that the use of the term "mix[ing] with a solution of a binding agent" in claims 1 and 2 of the '872 patent specifically excludes a dispersion. (Pls.' Br. Opp'n Defs.' Mot. Summ. J., at 12.) The issue, Plaintiffs contend, is a matter of claim construction that requires resolution of the meaning of the term as it would be understood by one of ordinary skill in the art.

In his fourth declaration submitted in this matter, Dr. Chowhan describes a dispersion as "a distribution of finely divided particles in a medium[,]" while describing a solution as a "single, homogeneous liquid, solid or gas phase that is a mixture in which components (liquid, gas, solid, or combinations thereof) are uniformly distributed throughout a mixture." (Fourth Decl. Dr. Chowhan, Ex. B, McGraw-Hill Dictionary of Scientific and Technical Terms, 627, 1274 (6th Ed., 2003).)

While Plaintiffs characterize the issue as one of claim construction, the critical issue before this Court is whether the disputed language presents a structural product limitation or describes a product characteristic that is a claim limitation. Scripps, 927 F.2d at 1583. In determining patentability, this Court construes the product as not limited by the process stated in the claims. See id. The language at issue, "mixed with a solution of a binding agent[,]" describes a process step. ('872 patent, col. 33, lines 31, 58.) For the purposes of the anticipation inquiry, a process step presents a claim limitation only if it establishes product characteristics that are claimed.

> While product-by-process claims are not limited to the product prepared by the process set forth in the claims, process steps may establish product characteristics which are claim limitations. In an infringement or validity analysis, characteristics or product properties imparted by process steps recited in product-by-process claims *are only relevant, however, to the extent that the resulting characteristics are claimed*.

Aventis, 335 F. Supp. 2d at 586 (citing E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433 (Fed. Cir. 1988)) (emphasis added).

Plaintiffs do not argue that "mix[ing] with a solution of a binding agent" presents a structural product limitation. Plaintiffs do not identify a product characteristic that is claimed. Moreover, Plaintiffs do not contend that use of a solution with a fully dissolving binding agent, rather than starch, in the wet granulation process makes any difference in the claimed pharmaceutical composition. Differences between prior art and claimed products "are only relevant . . . to the extent that the . . . characteristics are claimed." Aventis, 335 F. Supp. 2d at 582. The language at issue, "mixed with a solution of a binding agent[,]" does not present a structural product limitation or a product characteristic that is claimed.

As a matter of claim construction, Plaintiffs argue, the claims describe a pharmaceutical composition that contains a binding agent capable of forming a granulating solution and a pharmaceutical composition that does not contain a binder capable of forming a granulating solution falls outside the literal scope of the claims. However, construing the claims confirms that the language at issue describes a process step and does not present a product limitation or characteristic that is claimed. Furthermore, claim construction serves to demonstrate that Plaintiffs' interpretation of the term at issue conflicts with the specification and the testimony of Plaintiffs' own expert witness, Dr. Chowhan.

1. *Construing "A Solution of a Binding Agent"*

Claim construction is a matter of law to be resolved by the Court. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). Claim terms are presumed to have the ordinary and customary meanings ascribed to them by those of ordinary skill in the art. Sunrace Roots Enter. Co. v. SRAM Corp., 336 F.3d 1298, 1302 (Fed. Cir. 2003). A term's ordinary meaning must be considered in the context of intrinsic evidence, including the claims, the specification, and the prosecution history. 3M Innovative Props. Co. and Minnesota Mining and Mfg. Co. v. Avery Dennison Corp., 350 F.3d 1365, 1371 (Fed. Cir. 2003) (citations omitted).

The patent claims, specification, and prosecution history together constitute the intrinsic evidence of the claim's construction and "the most significant legally operative meaning of disputed claim language." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). In construing the terms of a patent, the court must examine the specification to determine whether the patentee used the claim term consistent with its ordinary meaning or acted as his own lexicographer in defining the term. See, e.g., Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998).

> Thus . . . it is always necessary to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning. The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication. . . . '[c]laims must be read in view of the specification, of which they are a part.' The specification contains a written description of the invention which must be clear and complete enough to enable those of ordinary skill in the art to make and use it. Thus, the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.

Vitronics Corp., 90 F.3d at 1582 (quoting Markman, 52 F.3d at 979).

2. *The Language of the Claims and the Specification*

Plaintiffs suggest that the term – mixed with a solution of a binding agent – as used in the claims, has the customary meaning that would be ascribed to it by one of ordinary skill in the art. According to Plaintiffs, the word "solution" requires reading the process step to describe a water soluble binder that goes into a solution or dissolves. Plaintiffs contend that "[t]his construction of claims 1 and 2 is mandated by the ordinary meaning of the claim term 'solution,' as well as by the specification." (Pls.' Br. Opp'n Defs.' Mot. Summ. J., at 11.) Plaintiffs refer the Court to the definitions of dispersion and solution in the McGraw-Hill Dictionary of Scientific and Legal Terms, defining a dispersion as a distribution of finely divided particles located in a medium and defining a solution as components that are uniformly dispersed throughout a mixture. (Fourth Decl. Dr. Chowhan, Ex. B, McGraw-Hill Dictionary of Scientific and Technical Terms, at 627, 1274.)

The specification of the '872 patent teaches that the following binders may be used in practicing claims 1 and 2: gelatin, polyvinylpyrrolidone, pregelatinized starch, povidone, and cellulose derivatives. ('872 patent, col. 13, lines 26-29.) The examples of permissible binders explicitly include pregelatinized starch, the very binder that Plaintiffs argue cannot be used to practice claims 1 and 2. In the discussion of the preferred combination of inert ingredients, the '872 patent describes combinations that include pregelatinized starch as a binder. ('872 patent, col. 13, lines 52-57.) Finally, Table 5 of the patent lists pregelatinized starch among the preferred inert ingredients. ('872 patent, col. 14, lines 10-29.)

This Court finds Plaintiffs' characterization of the claim language – "mix[ing] with a

solution of a binding agent"– to be inconsistent with the language in the specification. In order to reach the conclusion Plaintiffs proffer, this Court would have to disregard the language in the specification of the '872 patent and the testimony of Plaintiffs' expert witness, Dr. Chowhan.

An examination of the intrinsic evidence reveals that Plaintiffs cannot demonstrate that a soluble solution of a binding agent is a characteristic of claims 1 and 2. The query raised by an anticipation defense is whether prior art describes every limitation of the claims. In re Cruciferous Sprout Litig., 301 F.3d 1343, 1349 (Fed. Cir. 2002). Here, Plaintiffs have failed to establish that a soluble binder is a limitation of the claims. No intrinsic evidence supports Plaintiffs' argument that the claims distinguish between soluble and insoluble binders. This Court finds that the mixing of a solution of a binding agent is a process step and not a structural limitation or a characteristic that imparts a limitation.

3. *Extrinsic Evidence*

Extrinsic evidence consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treaties. Markman, 52 F.3d at 980. Plaintiffs argue that "[p]ersons of skill in the art understand that certain binding agents can form granulating solutions because the binding agent is soluble in the granulating liquid, while other binding agents are insoluble and are dispersed within or wetted by the granulating liquid." (Fourth Decl. Dr. Chowhan, at ¶22.) In support of this argument, Plaintiffs submit the Fourth Declaration of Dr. Chowhan, who explains that "it is readily understood by one skilled in the art that starch and pregelatinized starch are not soluble excipients, but form dispersions." (Id.) Dr. Chowhan's Fourth Declaration in support of Plaintiffs' nascent assertion that the term "mix[ing] a solution of a binding agent" requires a soluble excipient is, however, inconsistent with his

earlier declarations and sworn testimony.[8]

During the Markman hearing, Dr. Chowhan testified that "any binder can be used" to practice claims 1 and 2.[9] While his testimony could be regarded, in isolation, as the conventionally flippant response of an expert witness on cross-examination, Dr. Chowhan's later testimony further affirms his opinion that the binders listed in the specification of the '872 patent can be used to practice claims 1 and 2. In response to subsequent questions, Dr. Chowhan's testimony – which specifically addresses the formation of granules in a wet granulation– suggests no significant issues arise out of the use or substitution of the binders listed in the specification. (9/21/04 Hr'g Tr. at 67-69.) As noted above, the specification clearly includes pregelatinized starch as a binding agent that may be used to practice claims 1 and 2.

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[8] In addition to the inconsistencies discussed below, Defendants indicate that Plaintiffs' responses to discovery requests are also inconsistent with their argument that a starch binder may not be used to practice claims 1 and 2. Defendants posit that Plaintiffs initially responded to Defendant Barr's First Set of Interrogatories, Interrogatory No. 2 - inquiring as to the elements of the claims of the patent-in-suit - by indicating that the fexofenadine hydrochloride layer in the ALLEGRA® tablet composition "is prepared wherein fexofenadine hydrochloride, microcrystalline cellulose (a diluent) and croscarmellose sodium (a disintegrant) are mixed with pregelatinized starch and water (a solution of a binding agent)." (Pls.' Resps. to Def. Barr Labs., Inc.'s First Set of Interrogs., June 1, 2004, at 27.)

Aventis very recently amended its responses to Barr's First Set of Interrogatories, substituting the following for the above initial response to Interrogatory No. 2: "[t]he '872 patent is not listed in the Orange Book for ALLEGRA® and ALLEGRA-D® tablets, and plaintiffs do not contend that the '872 patent covers such products." (Pls.' First Am. Resps. to Def. Barr Labs., Inc.'s First Set of Interrogs., Dec. 28, 2004, at 21.)

[9] Q: Now, as I understand it, it's your opinion that any of the well-known binders can be used in practicing Claims One and Two of the '872 patent to make granules. Is that right?

A: Yeah, any binder can be used.

(9/21/04 Hr'g Tr. at 67:6-9.)

Moreover, Dr. Chowhan's Declaration in Support of Plaintiffs' Opposition to Defendants' Motions for Summary Judgment reflects his opinion that mannitol and corn starch – binders used in Dr. Reddy's formulation – could be used as a binding agent when practicing the process steps in claims 1 and 2. (Decl. Dr. Chowhan in Support of Pls.' Opp'n Defs.' Mot. Summ. J., Aug. 7, 2003, at ¶ 39.) In response to the allegation of infringement, Dr. Reddy's had asserted that its tablet formulation did not contain a binder. Dr. Chowhan concluded that Dr. Reddy's position, that its formulation did not contain a binder, was inconsistent with his "long experience in the field." (Id.) Dr. Chowhan determined that "mannitol likely function[ed] as the binding agent in Dr. Reddy's formulation." (Id.)

Dr. Chowhan concluded that Dr. Reddy's "process is consistent with a wet granulation process which uses a binding agent to form granules from individual particles." (Id.) Dr. Chowhan further concluded that "regardless of which ingredient used by Dr. Reddy is functioning as a binder, . . . Dr. Reddy's process uses a wet granulation process and a binding agent as set forth in claims 1 and 2 of the '872 patent." (Id. at ¶¶ 40-42.) Dr. Chowhan's conclusions that Dr. Reddy's used mannitol or corn starch as a binder and that Dr. Reddy's process infringed claims 1 and 2 of the '872 patent contradicts the conclusion in Dr. Chowhan's Fourth Declaration that starch may not be used to practice claims 1 and 2.[10]

As the Federal Circuit noted in Scripps, "claims must be construed the same way for

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[10] According to Dr. Chowhan's Fourth Declaration,

> Claims 1 and 2 of the '872 patent require that the binding agent be one that can form a granulating solution. A formulation in which the binding agent is incapable of forming a granulating solution cannot be made by the process of claims 1 and 2. Accordingly, the language of claims 1 and 2 excludes the use of starch paste and pregelatinized starch as binders because they do not form solutions of a binding agent.

(Fourth Decl. Dr. Chowhan ¶ 24.)

validity and infringement[.]" 927 F.2d at 1583. See also Bristol Myers Squibb Co. v. Ben Venue Labs, Inc., 246 F.3d 1368, 1373 (Fed. Cir. 2001) ("[T]hat which would literally infringe if later anticipates if earlier." (citation omitted)). The process step of "mix[ing] with a solution of a binding agent" does not present a structural product limitation or describe a product characteristic that imparts a limitation. This Court finds unavailing Plaintiffs' argument that the '061, '129, '353 and '693 patents fail to disclose a soluble excipient and therefore, fail to anticipate.

Plaintiffs thus fail in arguing that the use of a starch binder causes the prior art patents to fall outside the scope of claims 1 and 2. This Court finds that the '061, '129, '353, '605 and '693 patents disclose each and every element of claims 1 and 2 of the '872 patent. No genuine issues of material fact remain in dispute and therefore, this Court grants Defendants' motion for summary judgment.

C. *Arranged As In The Claim*

Additionally, Plaintiffs argue that the '129, '353 and '693 patents do not anticipate because they fail to disclose each of the elements of the claimed invention "arranged as in the claim." (Pls.' Br. Opp'n Defs.' Mot. Summ. J., at 14.) According to Plaintiffs, the '129, '353 and '693 patents may not be found to anticipate merely because each contains, somewhere in its text, the terms pharmaceutical composition, fexofenadine hydrocholride, a diluent, a disintegrant, a binding agent, and a lubricant. (Id. at 16.)

Plaintiffs contend that Defendants may not merely combine disclosures, gathering elements from different parts of references to prove anticipation. During oral argument, Plaintiffs argued that the language "arranged as in the claim" must be interpreted to impose a requirement regarding the serial recitation or organization of the elements of the claim or else the

language would be superfluous. Plaintiffs further argue that Example 10 of the '129 patent describes a tablet formulation with a different active ingredient (ethyl 4-[4-[4-(hydroxydiphenylmethyl)-1-piperidinyl]-1-hydroxybutyl]-α-α dimethylbenzeneacetate) than the active in the '872. Defendants' argument in favor of anticipation, Plaintiffs contend, requires substituting fexofenadine hydrochloride disclosed in a different example for the active ingredient in Example 10. According to Plaintiffs, one skilled in the art would understand that a formulation that is described as suitable for a particular active ingredient may not be suitable for a different active ingredient. (Fourth Decl. Dr. Chowhan ¶¶ 12-15, 30.) Plaintiffs raise a similar argument regarding Example 5 of the '693 patent.

The Federal Circuit has explained that to anticipate a claim, a reference must disclose every element of the challenged claim. See PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1566 (Fed. Cir. 1996). Further, the reference must be sufficiently clear so as to prove the existence of each and every element in the reference. See Motorola, Inc. v. Interdigital Tech. Corp., 121 F.3d 1461, 1473 (Fed. Cir. 1997). The standard reflects from the well-recognized requirement that the exact subject matter claimed must be described by the allegedly anticipating reference. C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1349 (Fed. Cir. 1998); Richardson v. Suzuki Motor Co. Ltd., 868 F.2d 1226, 1236 (Fed. Cir. 1989); Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 894 (Fed. Cir. 1984).

One of the earliest uses by the Federal Circuit of the language "arranged as in the claim" appears to have been in Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 1542 (Fed. Cir. 1983). The Federal Circuit appears to have used the language in several decisions since Connell v.

Sears.[11] None of these precedents suggests the interpretation of the language that Plaintiffs propose.

The language, "arranged as in the claim," does not create a distinct inquiry in the anticipation analysis. The standard for

> [a]nticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim. In deciding the issue of anticipation, the trier of fact must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference.

Lindemann, 730 F.2d at 1458 (citations omitted).

Plaintiffs cannot refer this Court to any precedent supporting their argument that the language "as arranged in the claim" imposes a separate requirement in the anticipation standard. Plaintiffs direct the Court to Novo Nordisk North America v. Beckton Dickson & Co. and note that the case is instructive. 96 F. Supp. 2d 309, 311-12 (S.D.N.Y. 2000). In their opposition papers, Plaintiffs argue that the Novo Nordisk Court "den[ied] summary judgment and reject[ed] anticipation because a necessary element of a claimed combination was listed separately in another portion of the asserted reference." (Pls.' Br. Opp'n Defs.' Mot. Summ. J., at 15.)

Careful review of the Novo Nordisk decision, however, reveals that the court denied

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[11] Rosco, Inc. v. Mirror Lite Co., No. 03-1562, 2005 WL 96838, at *4 (Fed. Cir. Jan. 19, 2005); Brown v. 3M, 265 F.3d 1349, 1351 (Fed. Cir. 2001); Sandt Tech., Ltd. v. Resco Metal and Plastics Corp., 264 F.3d 1344, 1351 (Fed. Cir. 2001); Karsten Mfg. Corp. v. Cleveland Golf Co., 242 F.3d 1376, 1383 (Fed. Cir. 2001); ATD Corp. v. Lydall, Inc., 159 F.3d 534, 545 (Fed. Cir. 1998); C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1349 (Fed. Cir. 1998); In re Bond, 910 F.2d 831, 832 (Fed. Cir. 1990); Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 1236 (Fed. Cir. 1989); Carella v. Starlight Archery and Pro Line Co., 804 F.2d 135 (Fed. Cir. 1986); Panduit Corp. v. Dennison Mfg. Co., 774 F.2d 1082 (Fed. Cir. 1985); Jamesbury Corp. v. Litton Indus. Prods., Inc., 756 F.2d 1556, 1560 (Fed. Cir. 1985); Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 716 (Fed. Cir. 1984); Lindemann, 730 F.2d at 1458.

summary judgment because a genuine issue of material fact remained in dispute - Plaintiff and Defendant's experts offered contrary opinions regarding whether an article, featuring a needle hub for a 27-gauge needle in an insulin injecting system on the cover of an article that contained a written description of a 30-gauge needle in the text, disclosed the 30-gauge needle used in the challenged patent.[12] 96 F. Supp. 2d at 309-312. In its analysis on the issue of anticipation, the Novo Nordisk Court noted that these disputed issues of material fact prevented the court from determining whether the prior art taught each and every element of the claimed invention; whether the prior art disclosed the elements as arranged in the claims; and whether the prior art was enabling. Plaintiffs emphatically refer this Court to the enumerated grounds for denying summary judgment. Plaintiffs argue that the Court enumerated, as a distinct ground for denying summary judgment, the question of "whether the prior art disclosed the elements as arranged in the claim." Id. at 312.

The standard for anticipation clearly requires that prior art disclose all limitations of the claimed invention. Lindemann, 730 F.2d at 1458. This Court shall not, however, read the standard to require the newly proposed serial obligations that Plaintiffs advocate. The Federal Circuit has rejected attempts by plaintiffs to read additional requirements into the anticipation standard. See In re Bond, 910 F.2d 831, 832-33 (Fed. Cir. 1990) (rejected attempt to require that prior art present an *ipsissima verba*, verbatim, recitation of the limitations).

While there may be instances in which the order of the elements in a challenged claim

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[12] While the Novo Nordisk Court also notes that a genuine issue of material fact remained regarding whether the prior art disclosed the elements "as arranged" in the claimed device, the court did not suggest that the language "as arranged" was intended to have a meaning distinct from that traditionally assigned to it. 96 F. Supp. 2d at 312.

contributes to the claim's novelty, the order or organization of the elements is not at issue here. Plaintiffs' contentions reflect an understanding that all of the elements in claims 1 and 2 must appear in a single example of each prior art reference in order for the prior art to anticipate. The Federal Circuit has explicitly rejected the notion that anticipation requires that all limitations of the claims are described in a single example of the prior art reference. Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1348 (Fed. Cir. 2004) (citing In re Spada, 911 F.2d 705, 708 (Fed. Cir. 1990)). According to the Federal Circuit, "[a]nticipation requires that all limitations of the claimed invention are described in a single reference, rather than a single example in the reference." Id. at 1348.

This Court declines Plaintiffs' invitation to adopt an additional element in the anticipation standard requiring that all elements in an anticipating claim appear in a single example within the reference. This Court finds that each of the cited prior art references discloses each and every limitation of claims 1 and 2, and therefore, under 35 U.S.C. § 102(b), the references anticipate claims 1 and 2 of the '872 patent.

CONCLUSION

Based on the above reasoning, this Court GRANTS Defendants' motion for summary judgment of invalidity of claims 1 and 2 of the '872 patent. Defendants have demonstrated by clear and convincing evidence that one of ordinary skill in the art would interpret the cited references, the '605, '061, '353, '693 and '129 patents, as disclosing each and every limitation of the claimed invention. Claims 1 and 2 of the '872 patent are invalid as anticipated and therefore, Defendants' motion for summary judgment is GRANTED.

S/Joseph A. Greenaway, Jr.
JOSEPH A. GREENAWAY, JR., U.S.D.J.

Dated: May 31, 2005